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Assessing some of the associations with perinatal mortality at Kamuzu central hospital in Lilongwe, Malawi.

By

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28th November 2012`

Declaration

I, Elled Mwenyekonde, declare that this thesis embodies only my original work except where acknowledgement indicates otherwise and that no part of it has been or is being submitted for a degree at any other university.

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Date : 28th November 2012

The work for this thesis was done in the School of Child and Adolescent Health of the University of Cape Town.

Dedication

This dissertation is dedicated to my loving wife Thokozani who offered me financial and psychological support, and above all else made sure that I finish my studies. May the GOOD LORD BLESS HER ABUNDANTLY.

University of Cape Town

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List of abbreviations

AIDS	: Acquired Immune Deficiency Syndrome
ANC	: Antenatal Care
ART	: Antiretroviral Therapy
BEmOC	: Basic Emergency Obstetric Care
BH	: Bwaila Hospital
BW	: Birth Weight
CA	: Congenital abnormalities
CI	: Confidence Interval
CS	: Caesarean Section
ELBW	: Extremely Low Birth Weight
ENND	: Early Neonatal Death
ENNMR	: Early Neonatal Mortality Rate
FSB	: Fresh Stillbirth
HIV	: Human Immunodeficiency Virus
HRECUCT	: Human Research Ethics Committee of University of Cape Town
KCH	: Kamuzu Central Hospital
LBW	: Low Birth Weight
LNND	: Late Neonatal Death
MDG	: Millennium Development Goal
MDHS	: Malawi Demographic Health Survey
MSB	: Macerated Stillbirth
NHSRC	: National Health Sciences Research Committee
NND	: Neonatal Death
OR	: Odds Ratio
PD	: Perinatal Death
PIH	: Pregnancy Induced Hypertension
PNM	: Perinatal Mortality
PNMR	: Perinatal Mortality Rate
PPIP	: Perinatal Problem Identification Programme
QECH	: Queen Elizabeth Central Hospital
SB	: Stillbirth
SBR	: Stillbirth Rate
SSA	: Sub-Saharan Africa
SVD	: Spontaneous Vertex Delivery
VE	: Vacuum Extraction
WHO	: World Health Organization

Abstract

Background: Worldwide, over 130 million babies are born annually. Of these, about 6.3 million die in the perinatal period annually. This gives a perinatal mortality rate (PNMR) of 48/1000 births. Most perinatal deaths (PDs) occur in developing countries. Malawi's PNMR is estimated at 40/1000 births. The study objectives were to: determine the prevalence of perinatal mortality (PNM) and causes of early neonatal deaths (ENNDs), describe socio-demographic factors of mothers with PNM and assess some of the associations with PNM at Kamuzu Central Hospital.

Methods: The study employed a retrospective design of secondary data, collected from patients' files, of the deliveries from 1st July 2010 to 30th June 2011. Data were captured and entered on MS Access and analysed using STATA 11.0. Chi-square test, univariate and multivariate logistic regression analyses were used to describe some of the associations with PNM.

Results: A total of 2,294 deliveries were analysed. PNMR was 58.4 per 1000 births. ENNDs were caused by prematurity (52%) and asphyxia (24%). The factors that were independently associated with PNM were living in semi-urban areas (OR: 22.83, CI: 4.40-118.45), birth weight of 1000g-1499g (OR: 14.87, CI: 4.45-49.77), parity 2 (OR: 0.20, CI: 0.04-0.92), parity of ≥ 5 (OR: 5.51, CI: 1.54-19.68), breech and caesarean section (CS) deliveries (breech: OR: 5.30, CI: 2.16-13.0, C/S: OR: 1.80, CI: 1.15-2.81) and Apgar scores of 1-3 (OR: 23.09, CI: 1.62-329.97).

Conclusion: Kamuzu Central Hospital (KCH) had a high PNMR which is more than the national average of 40 per 1000 births. The high rate could be attributed to complicated cases handled by the hospital which are referred from other facilities. Therefore, improving health workers' skills in the management and recognition of foetal problems during labour, proper management of breech, family planning and resource allocation in perinatal care coupled with good referral systems and timely interventions can help to reduce PNM at KCH.

1.1 Introduction and background information

Worldwide, over 130 million babies are born annually (WHO 2006, p. 1). In 2006, the World Health Organization (WHO) estimated that 4 million newborns die in the first 4 weeks of life and out of these, 3 million deaths occurs during the first week of life. Another 3.3 million are stillborn resulting in about 6.3 million PDs giving a global PNMR of about 48 per 1, 000 births (WHO 2006, p. 1; Benjamin, Sengupta & Singh 2009, p. 13). Nearly 60 percent of all PDs are stillbirths (SBs) of which many are preventable (Smith & Fretts 2007, p. 1715). SBs are defined as infants born showing no signs of life at birth, weighing $\geq 500\text{g}$ after delivery (Smith & Fretts 2007, p. 1715; Vaishali & Pradeep 2008, p. 314) and ENND is defined as a death from birth up to and including day seven. In Malawi, SBs are defined as foetal deaths in pregnancies lasting seven or more months (MDHS 2011, p. 100). PNMR (all SBs and ENNDs) is defined as the number of PDs per 1000 births and is a useful indicator of access to quality of antenatal, intrapartum and neonatal care (Meguid & Mwenyekonde 2005, p. 11; Gordon & Fretts 2007, p. 1715).

Although PNM is a global problem, there are significant differences in the PNMR between developed and developing countries (Meguid & Mwenyekonde 2005, p. 11). For instance, 99 percent of all neonatal deaths (NNDs) occur in developing countries with 27 percent occurring in the least developed countries. In developing countries, the risk of death in the neonatal period is 6 times greater than in developed countries while in the least developed countries it is over 8 times higher (Lawn, Cousens & Zupan 2005, p. 891; WHO 2006, p. 1). Furthermore, intrapartum still-birth rates (SBR) of less than 1 per 1000 births are usual in developed countries while in Sub-Saharan Africa (SSA) and South Asia there is a 50 fold increase in this number (Lawn, Cousens & Zupan 2005, p. 892; WHO 2006, p. 1; McClure, Nalubamba-Phiri &

Goldenberg 2006, p. 83). For example, in 2000 Cote d' Ivoire, a low income country, had a PNMR of 96 per 1000 births while Sweden, a high income country, had a PNMR of 5 per 1000 births (WHO 2006, p. 30-33). These differences in the PNMR have been associated with varying levels of socioeconomic development, availability and quality of health care between countries and region.

The 2010 Malawi Demographic Health Survey (MDHS) estimated the PNMR of Malawi to be 40 per 1000 births (MDHS 2011, p. 100). This rate is similar to the findings by WHO which showed that Malawi has a PNMR of 43 per 1000 births (WHO 2006, p. 31). It is likely that PNMR for Malawi in the year 2006 was higher than the WHO estimated rate. At KCH it is difficult to calculate PNMR because there is no segregation of ENNDs and late neonatal deaths (LNNDs). However, the rate could be higher than other health facilities considering that KCH is a referral hospital which receives complicated cases from elsewhere. This shows that the burden of PNM has affected Malawian health facilities and communities.

To address the problem of NNDs in developing countries, Malawi was one of several countries which, in 2000, adopted Millennium Development Goal (MGD) number 4 as the target goal to achieve. It is clear that the MDG number 4 (which calls for a reduction in under-five mortality by two-thirds by 2015) will not be met without substantial reductions in neonatal mortality (Galjaart 2007, p. 6; Lawn et al. 2008, p. 410). Although a reduction in SBs can not lead to the achievement of MDG-4, but in this study, both SBs and ENNDs were analysed as both are components of PNM. Furthermore, most of the conditions which result in SBs are also responsible for ENNDs and they are difficult to distinguish from each other (Kinney et al. 2010,

p. 3). PNM was chosen because it is a useful indicator of access to quality antenatal, intrapartum and neonatal care.

This study aimed at assessing some of the associations with PNM in a Malawian context, especially at KCH, as there was a dearth of information in this regard. The study results can assist in informing health policy makers in improving maternal and neonatal service delivery. It can also assist the health workers in knowing which women are at risk of having a PD thereby leading to good clinical care of the patients. The results can also act as a baseline for future studies and other improvement processes related to this topic.

1.2 Profile of Malawi

1.2.1 Geography

Malawi is a landlocked country in the SSA. It is bordered to the north and northeast by the United Republic of Tanzania; to the east, south, and southwest by the People's Republic of Mozambique; and to the west and northwest by the Republic of Zambia (MDHS 2011, p. 1).

The country is 901 kilometers long and ranges in width from 80 to 161 kilometers. The total area is 118,484 square kilometers of which 94,276 square kilometers is land area. The remaining area is composed of Lake Malawi, which is about 475 kilometers long and runs down Malawi's eastern boundary with Mozambique (MDHS 2011, p. 1).

The country is divided into three regions: the Northern, Central, and Southern Regions. There are 28 districts in the country. Lilongwe is the capital city of Malawi. Six districts are in the Northern Region, nine are in the Central Region, and 13 are in the Southern Region. Administratively, the districts are subdivided into traditional authorities, presided over by chiefs.

Each traditional authority is composed of villages, which are the smallest administrative units, and the villages are presided over by village headmen (MDHS, 2011, p. 1).

The MDHS (2011) estimated the population of Malawi to be 13.1 million with a population density of 139 persons per square kilometer. About 15 percent of the total population lives in urban areas.

1.2.2 Economy

The economy of Malawi is based primarily on agriculture, which accounts for 30 percent of the gross domestic product. The country's major exports are tobacco, tea, and sugar. They account for approximately 85 percent of Malawi's domestic exports. In 2009, the agricultural sector achieved growth of 13.9 percent. Tobacco production was high following favourable prices that were offered at auction sales in the 2008 marketing season. In 2010, estimated growth slowed to 1.3 percent because of dry spells and heavy rains (MDHS 2011, p. 1).

1.2.3 Maternal health care services

In Malawi, a woman who attended antenatal care (ANC) is considered to have been given a package which is comprised of iron tablets, intestinal parasites drugs, informed about signs of pregnancy complications, weight recorded, blood pressure measured, urine sample take, blood sample taken and information on which foods to eat (MDHS 2011, p. 106).

According to the 2010 MDHS, ninety-five percent of women age 15-49 received ANC from a skilled attendant (doctor, clinical officer, nurse, or midwife) at least once during their last pregnancy. Five percent received ANC from an unskilled attendant like a patient attendant (2%), health surveillance assistants and traditional birth attendants (1%). Two percent of women did not receive any ANC services.

There has been a decline in the proportion of women who did not receive ANC between the 2004 MDHS (5%) and the 2010 MDHS (2%).

Most births (73%) in Malawi are delivered in a health facility; 57 percent of deliveries occur in public sector facilities, and 16 percent in private sector facilities. A total of 24 percent of births occur at home. The majority of births are assisted by a skilled health attendant (71%). Other deliveries were reported to have been assisted by traditional birth attendant (14%), relative or friends (9%), patient attendant (2%), none (3%) (MDHS, 2011, p. 110).

1.2.4 Maternal & Child health indicators

Indicators	Measure
Infant Mortality Rate	66 per 1000 live births
Maternal Mortality Ratio	675/100, 000 live births
Neonatal mortality rate	31 per 1000 live births
Perinatal mortality rate	40 per 1000 births
Under-five mortality rate	112 per 1000 live births

Source: *Malawi Demographic Health Survey 2011*

1.2.5 Study setting

The study was carried out at KCH maternity wing, Lilongwe, Malawi, a tertiary care hospital. It serves as a referral hospital for the district hospitals within central region. In addition, it also serves as a teaching hospital for students from Kamuzu College of Nursing and Malawi College of Health Sciences. The maternity hospital became operational in June 2010 after its detachment from Bwaila Hospital (BH), which is now a district maternity hospital. The study reviewed data

from 1st July, 2010 to 30th June, 2011. During this period, the hospital recorded 2307 deliveries. It is expected that the number of deliveries will increase in future due to high demand for maternal services at the hospital.

1.3 Problem statement and justification

Although several studies have highlighted determinants of PNM, most of these were conducted outside Malawi. In Malawi, only two studies were found relevant to this study and they served as a basis for the motivation of this study.

The first study was done in Mangochi, a district in the southern region of Malawi, by McDermott, Stekette & Wirima (1996) on “Perinatal mortality in rural Malawi”. In this prospective population-based study, it was found that syphilis, nulliparity, a history of a PD and low socioeconomic status were some of the factors that were associated with PDs. But, while acknowledging the above study results, the researcher believed that it was essential to conduct a hospital based study within the central region which will provide current information pertaining to PNM. Mangochi and Lilongwe have different socio-demographic characteristics of the population hence the importance to carry out similar study in Lilongwe. Furthermore, considering that Malawi government set national goals and targets there is a need to assess the extent of achievement of these goals and targets and compare the progress.

The second study was a prospective observational study on “Stillbirths and hospital early neonatal deaths at Queen Elizabeth Central Hospital, Blantyre-Malawi”. The study was done at Queen Elizabeth Central Hospital (QECH) in the southern region of Malawi by Metaferia and Muula (2009). The study was descriptive in nature and no strengths of association between exposure (dependent variable) and disease (independent variable) were analysed. Therefore,

there was a need for this study to further analyse the associations of PNM at KCH by exploring the association of different variables with PNM.

The raw data at KCH estimated the prevalence of neonatal mortality to be 122 per 1,000 live births and this was three times higher than the national average of 40 per 1000 births. The actual rate could be lower than this considering that there is no segregation between ENNDs and LNNDs at the hospital. However, the high prevalence could also show that the burden of NNDs is evident at KCH due to several factors hence the need to carry out this study.

The study results can help to equip midwives, clinical officers and doctors with knowledge on some of the associations with PNM at the hospital and this can potentially improve the care rendered to pregnant women and their newborn babies. Ultimately, it can assist in the formulation of appropriate recommendations and policies, planning for intervention strategies and resource allocation aimed at reducing PNM both at facility and national level. Lastly, the study results can provide baseline data for future studies and other improvement processes related to the topic.

KCH maternity wing was opened in June 2010. Previously, patients were attended to at BH which lies four kilometers away from KCH. Like KCH now, BH had similar burden of PDs because BH was a referral hospital for the central region prior to the construction of KCH maternity wing. This means there is an information gap regarding PNM at KCH maternity unit. Therefore, the study results would assist to fill-in this knowledge gap.

2.0 Literature review

This section of literature review assessed the causes and analysed some of the risk factors associated with PNM. The analysis highlighted the causes and some associations of PNM that are common in Malawi and most developing countries.

2.1 Causes of perinatal mortality

PNM is the sum of all PDs in relation to the total births (sum of all still born and live births). ENNDs are those that happen within seven days of delivery. SBs can either occur during labour or before labour. In Malawi, the two categories of SBs are differentiated by the skin appearance of the foetus. Fresh stillbirths (FSBs) are those SBs which happen during labour and have intact skin while macerated stillbirths (MSBs) are SBs that happen before labour and have peeled off skin. The prevalence of SBs is seen as a general indicator of the quality of antenatal and intrapartum care (Meguid & Mwenyekonde 2005, p. 11; Froen et al. 2009, p. 2).

Fresh stillbirths

Complications developing during pregnancy and labour are important factors to determine foetal and neonatal survival and health (Yousfani et al. 2008, p. 204). FSBs are commonly caused by complications that arise during labour and delivery (Edmond et al. 2009, p. 434). The most common labour complications that are responsible for FSBs are hemorrhage, hypertension, sepsis, and obstructed labor (Kinney et al. 2012, p. 3). In a study conducted in Dabhade, it was found that pregnancy induced hypertension (PIH), eclampsia, abruptio placenta and preterm labor were labour complications that caused FSBs (Vaishali & Pradeep 2008, p. 316). These labour complications almost always cause foetal hypoxia which can result in foetal death, or, if the baby survives, long term neurological disability.

In addition to the known causes there are also other causes which are unknown or unexplained. This was reported from several studies which reported that 20-50 percent of FSBs are unexplained (Froen et al. 2009, p. 13; Shrestha & Yadav 2010, p. 86; Edmond et al. 2008, p. 435). The reason behind unexplained FSBs could be related to poor foetal monitoring during labour coupled with delayed response to abnormal foetal heart rate which results into birth asphyxia (BA). The failure to recognize the cause of death, in this case, could result to labelling FSBs as unexplained.

Macerated stillbirths

The causes of many MSBs are often unclear. For instance, in South Africa, it was found that half of all MSBs had unexplained causes while the rest were mainly caused by hypertension, APH, prematurity and intrauterine growth retardation (ed. Pattinson 2012, p. 36). In related studies from elsewhere, it was reported that many MSBs in developing countries were due to syphilis, malaria, congenital abnormalities (CAs), poor nutrition and sickle cell disease (McClure 2006, p. 85). In most developing countries, the causes of MSBs, which can be diagnosed and treated, are mostly syphilis and malaria. Most of developing countries routinely screen and treat pregnant women against these infections (Smith & Fretts 2007, p. 1717). In Malawi all ANC women are routinely screened for syphilis and treated for malaria. Conversely, it is a common practice to screen all women, with a MSB, against syphilis and malaria.

Early neonatal deaths

The causes of ENNDs are similar worldwide and WHO has estimated the global direct causes of NND to be prematurity (28%), severe infections (26%) and BA (23%) (WHO 2005, p. 894). In Pakistan and India, similar trends were observed. The studies found that prematurity (35%), CAs (23%), sepsis/infections (19%) and BA (16%) were the common causes of ENND (Mufti, Setna & Nazir 2006, p. 175-176; Sinha 2006, p. 189; Shrestha & Yadav 2010, p. 86). In South Africa, data from the Saving Babies Report for 2009 (ed. Pattinson 2011, p. 49), showed that the main causes of ENND, in babies with a birth weight (BW) of $\geq 1000\text{g}$, were BA (38%) and prematurity (30%). An analysis in SSA women showed that the common causes of newborn deaths in this region are: infections, BA and preterm births (Kinney et al. 2010, p. 4). This trend is common for most developing countries.

2.2 Analysis of some of the associations with perinatal mortality

There are many factors which potentially contribute to the occurrence of PNM (Hokororo 2009, p. 6). In this literature review, analysis of factors that are associated with PNM was done in-order to find these risk factors. The analysis was done under the framework which was related to: mother's socio-demographic factors, ANC factors, delivery process and labour complications, foetal and neonatal factors and health systems factors.

2.2.1 Socio demographic factors

Maternal age

Maternal age has been known to be associated with PNM from studies done in both developed and developing countries. Pregnant women that are less than 18 years old and more than 34 years have significantly higher PNMR than those within these ages. The results from a case control

study which was conducted at Mexican Institute of Social Security Hospital, on “Multivariate analysis of factors for stillbirth in Leon, Mexico” showed a higher risk of PNM in mothers who were older than 35 years (Romero-Gutierrez et al. 2005, p. 4). Similar results were also gathered from Zimbabwe and Nigeria (Feresu et al. 2005, p. 6; Fawole et al. 2011, p. 40). Women with advanced maternal age are more likely to suffer from various complications such as haemorrhage and obstructed labour which expose them to a PD. In order to be able to deal with possible labour complications in their late pregnancy women, in many developing countries, are sent to district hospitals maternity waiting homes where they can get easy access to emergency obstetrical care quickly (Lawson, Harrison & Bergstrom 2003). On the other hand several studies have shown that women less than 20 years old are more likely to have a PD than women between ages of 20 and 24 years old (Upadhyay et al. 2011, p. 1; ed. Pattinson 2011, p. 9; New Zealand Ministry of Health 2007, p. 23; Fawole et al. 2011, p. 39; Feresu et al. 2005, p. 4). The reason for higher PNM in this age group could be attributed to problems such as maternal hypertensive disease and obstructed labour which could be coupled with delayed labour progress. These problems are also known to increase the risk of PNM in these women.

Place of residence

Women who reside in rural areas have an increased risk of having PD. A study from Ludhiana in Punjab, found that the PNMR for women residing in rural and urban areas were 53/1000 births and 27/1000 births respectively (Benjamin, Sengupta & Singh 2009, p. 14). Similarly, studies from Tanzania and Zimbabwe found a higher PNMR in women who resided in rural and semi-urban areas than those from urban (Habib et al. 2008, p. 961; Emmanuel et al. 2011, p. 5). The high risk of PNMR in women residing in rural areas could be related to poor access to Basic Emergency Obstetric Care (BEmOC). These pregnant women walk longer distances not only in

search for health services but also in searching for quality health services which are not always available in the rural facilities thereby increasing their risk of having a PD.

In contrast, a community based prospective cohort study from Uganda recorded the PNMR of 68 per 1000 births and 33 per 1000 births for urban and rural areas respectively. The women in the urban areas had a 2.7 times higher risk of losing their babies in the perinatal period compared to those in the rural areas (Nankabirwa et al. 2011, p. 5). Although these study results seem to be different from other studies, it was observed that the study participants from the rural areas were those who lived close to the road and this improved their accessibility to health care services similar to urban residents. In another report by MDHS, it was reported that the PNMR was 45 deaths per 1000 births and 39 deaths per 1000 births in urban and rural areas respectively (MDHS 2011, p. 100). In the same MDHS it was reported that the neonatal mortality rate was 31 deaths per 1000 live births for urban areas and 34 deaths per 1000 live births for rural areas. Therefore, the finding of higher PNMR in the urban areas could be due to underreporting of community based PDs due to some cultural beliefs. In most cultures in Malawi, SBs and NNDs are not usually reported to the authorities because of the belief that they are not “human beings” and these deaths are highly secretive.

Maternal education

The maternal level of education is another socio-demographic risk factor that has also been identified to be associated with PNM. In studies from Tanzania, Ethiopia and Zimbabwe, it was reported that lack of maternal education was associated with a statistically significant risk of having a PD (Habib et al. 2008, p. 962; Emmanuel et al. 2011, p. 5; Chekol 2011, p. 14). Similar findings were obtained from a study which was conducted in Ludhiana in Punjab where it was found that higher maternal education was associated with decreased PNMR while mothers with

high illiteracy level were associated with a greater risk of having a PD (Benjamin, Sengupta & Singh 2009, p.14). This is because educated mothers may use health services more productively and effectively, may have better information regarding the health services available and may have more family resources which can be used when seeking health care while women with low socioeconomic status and poor education appear not to recognize the danger signs in pregnancy as an emergency and this reduces their health seeking behavior thereby increasing the risk of a PD (Seckin 2009, p. 13).

Occupation

The occupation of the mother can affect the outcome of pregnancy. Non-working mothers are more likely to have higher PNMR compared with working mothers. This is because non working mothers are economically dependent on their husbands and they wait for husbands to make a choice before they seek health services (Chekol 2011, p. 15). Furthermore, mothers who are not formally employed are prone to physical strain and other exposures which are the risks to the pregnancy as they often have to do much of the farming activity in rural areas. In contrast, studies in Bangladesh and Indonesia found that employed women experienced high PNMR compared to unemployed (Chowdhury et al. 2010, p. 120; Titaley et al. 2008, p. 12). This is because unemployed mothers are able to care for their newborns as compared to employed mothers and this put babies born to employed mothers to be at greater risk of various neonatal complications which lead to PDs. Therefore, it can be concluded that if mother's unemployment is coupled with better household income it can lead to better pregnancy outcome. This shows that whether the mother is employed or not the care of the newborn is crucial for its survival.

Maternal parity

Maternal parity, which is the number of times a mother has given birth, is another risk factor for PNM. Women who give birth for the first time and those who give birth for more than 5 times are more likely to have a PD compared to women falling within these parity extremes. In two studies which were done in Burkina Faso and Dublin, it was found that primiparous women were associated with a significantly increased risk of having a PD than multipara (Diallo et al. 2010, p. 5; Walsh et al. 2008, p. e2). On the contrary, a study in Leon, Mexico, showed an insignificant association between parity and PDs (Romero-Gutierrez et al. 2005, p. 4). This could have resulted from case control matching problems observed with this variable.

Higher parity (> 4 pregnancies) is also associated with increased likelihood of having a PD. This was observed from a systematic review study on “Stillbirth in developing countries” which showed that higher parity was associated with a greater risk of having a PD (McClure et al. 2006, p. 85). Women falling in the parity extremes have this increased risk of PNM because higher parity is associated with most labour problems and complications. This is why it is a policy for Malawi health system to deliver these women at secondary level where BEmOC services are available. However, other authors have reported that high parity is not a risk factor especially to women with good access to medical care but it becomes a risk factor when high parity, high child mortality and extreme poverty and deprivation are combined (Lawson, Harrison & Bergstrom 2003).

2.2.2 Antenatal care and maternal diseases/infections

Maternal history of a SB and an ENND

A maternal history of a SB and an ENND has been known to increase the probability of a PD in subsequent pregnancies. Women with previous obstetrical complications and a history of PNM

have high chances of having a repeat of these during next pregnancies. A study by Fretts et al. (2010, p. 594) found that women with a history of a SB had a significantly increased risk of an adverse outcome in future pregnancies. Similar findings were obtained from a case control study done in Zimbabwe. This study found that women with a history of a SB and an ENND had a 4 and 7 times greater risks of a PD in the following pregnancies respectively (Emmanuel et al. 2009, p. 5). In the study, history of a SB and abortion were associated with higher probability of a PD (Emmanuel et al. 2009, p. 5). Similar findings were reported in a retrospective cohort study in Zambia and a systematic review from developing countries (Stringer et al. 2011, p. 1156; McClure, Nalumbaba-Phiri & Goldenberg 2006, p. 84). These problems may reoccur especially if the causes of a previous PD were not identified and treated in time. Unless previous pregnancy problems are identified and treated, subsequent pregnancies would always be at greater risk of a PD. This is why a previous obstetric history is an important element to be considered in the management of obstetric patients, and important information to be obtained at the patient's first visit to the antenatal clinic.

In Malawi, one descriptive study found that 62.7 percent of mothers with a PD had a history of PD (Metaferia & Muula 2009, p. 1). In a related Malawian study, which was conducted in Mangochi, it was found that mothers with a previous PD had an odds ratio (OR) of 3.27 times greater risk than those without a history of a PD (McDemott, Steketee & Wirima 1990, p. 167). From these studies it shows that a history of a PD can be associated with an adverse outcome of future pregnancies.

Antenatal care attendance

Antenatal care is the care that is given to a pregnant woman from the time that conception is confirmed until the beginning of labour (Fraser, Cooper & Nolte, 2006). Quality of ANC can be measured by the number of times a woman receives ANC and the services that she receives. Hence,

ANC attendance is associated with better perinatal outcome. This shows that women, who attend ANC once, usually have better pregnancy outcome compared to those who do not attend ANC. This is because the women receiving ANC are well educated on danger signs of pregnancy such that they are more likely to report to the health facility when they have a problem unlike women without ANC. Furthermore, these women are examined for health problems which could arise during pregnancy, and these can be treated early to prevent an adverse outcome. In Malawi, ANC attendance means that a woman has received a package comprising of iron tablets, intestinal parasites drugs, informed about signs of pregnancy complications, weight recorded, blood pressure measured, urine sample take, blood sample taken and information on which foods to eat (MDHS 2011, p. 106). In this regard, it is believed that mothers who attend ANC regularly are more likely to have better perinatal outcome than irregular attendees. Empirical studies have indicated that the increased ANC attendance results in better health of infants. In Zimbabwe, two studies found that women who attended ANC had less chances of having a PD than those who did not attend ANC (Emmanuel et al. 2011, p. 5; Feresu et al. 2005, p. 5). Similarly, in Nigeria, women who did not attend ANC had a 1.74 times higher risk of a PD than those who attended ANC (Fawole et al. 2011, p. 40; Bhattacharyya & Pal 2012, p. 268).

Maternal Human Immunodeficiency Syndrome infection

Human Immunodeficiency Virus (HIV) infection of the mother has been shown to be associated with a PD in some studies. The combination of HIV infection and pregnancy is known to increase the risk of death in both the mother and the newborn. Furthermore, HIV compromises maternal immunity and this low immunity is transferred to the newborn leading to reduced chances of survival (Emmanuel et al. 2011, p. 8). A study from Zimbabwe reported that the

mother's HIV infection was an independent risk factor of PNM with an OR of 5.6 times greater risk in HIV infected mothers than non HIV infected mothers (Emmanuel et al. 2011, p. 5). In South Africa it was reported that HIV infected mothers were twice likely to have SBs than HIV negative mothers (Baleta 2011, p. 1304). However, in a retrospective cohort study in Zambia, it was found that HIV infection was not associated with an increased risk of stillbirth (Stringer et al. 2011, p. 1156). Furthermore, HIV infection can cause maternal Acquired Immune Deficiency Syndrome (AIDS) thereby increasing the risk of death to the pregnancy or the newborn. In Malawi HIV pregnant women are put on Antiretroviral Therapy (ART) in-order to improve their immunity thereby increasing chances of maternal and child survival.

2.2.3 Delivery process factors

Labour induction/augmentation

Induced or augmented labour is mostly associated with labour complications and this can result in a poor pregnancy outcome. In Tanzania, women with induced/augmented labour had a greater risk of a PD compared to those with spontaneous labour and this increased the risk of BA in newborns (Kidanto et al. 2009, p. 5). Induced and augmented labour can cause hyper-stimulation of the uterus which can sometimes result to uterine rupture and foetal hypoxia thereby risking the foetal wellbeing. In this regard, it is advisable to rule out contraindications to induction/augmentation before giving the drug.

Mode of delivery

The mode of delivery is often associated with the condition of the newborn at birth. Infants born through breech delivery carry a greater risk of a PD than those born through spontaneous vertex delivery (SVD). A study in Zambia found a 4.5 times greater risk of a SB in breech deliveries compared to other mode of deliveries (Stringer et al. 2011, p. 1156). Similar results were

obtained from India and London studies (Bhattacharyya & Pal 2012, p. 269; Smeeton et al. 2004, p. 5). Breech deliveries are associated with birth trauma and prolonged labour and this increases the risk of BA and a PD. A Cochrane literature review by Darmstadt et al. (2009, p. 24) showed that planned CS was associated with a statistically significant reduction in PDs. Similarly, vacuum extraction (VE) was found to reduce the risk of a PD in mothers awaiting emergency CS (Kidanto et al. 2009, p. 7). This could mean that although VE seems to be a known risk factor for a PD but in this study the results were different.

Complications in labour

Labour complications have been reported as the most important contributor of PNM and are regarded as one of the most important determinants of foetal and neonatal survival (Kidanto et al. 2006, p. 75; Edmond et al. 2006, p. 435). Complications which occur during labour and which affect the foetus often result in either a stillborn infant or an ENND. Complications in labour can result from maternal illness like preeclampsia, or from problems related to labour process itself such as foetal distress and prolonged labour. Both of these have an effect on the foetus leading to a PD. Complications such as haemorrhage and eclampsia will almost always compromise foetal oxygenation leading to foetal hypoxia then death. In Ghana, Edmond et al. (2006, p. 435) found that labour complications were responsible for more than half of PDs (59.3%). In a case control study in Brazil and a prospective cohort study in Karachi, it was also found that mothers with labour complications had an increased risk of PDs (Shoeps et al. 2007, p. 7; Jehan et al. 2007, p. 257). Similarly, in Zimbabwe it was reported that OR of PDs was about 9 times higher in women with labour complications compared to those without labour complications (Emmanuel et al. 2011, p. 16). This is why it is important to deliver babies sooner rather than later when a complication develops in labour because a delay would increase the risk of PNM. Since most

labour complications are associated with PNM it is imperative that labour complications be prevented or treated early before the foetal condition is compromised. Labour complications are usually better managed at secondary or tertiary levels of care where emergency obstetric care is available.

2.2.4 Foetal and neonatal factors

Gestation age

Preterm gestational age is directly related to low birth weight (LBW) and preterm babies are more likely to have a LBW hence are also at a greater risk of PNM. One study found that preterm newborns had a higher risk of a SB compared to term newborns (Feresu et al. 2004, p. 158). The study also found that multiple pregnancies significantly increased the risk of preterm delivery in pregnancies less than 38 weeks and also a greater risk in pregnancies less than 33 weeks. Physiologically, babies born preterm have high chances of lung immaturity with hyaline membrane disease which increases the risk of PNM. Furthermore, immaturity of other organ systems also puts the preterm baby at an increased risk of a PD.

Multiple pregnancy (plurality of foetus)

The number of foetuses in the uterus can have an influence on their outcome. Multiple pregnancies can result in complications such as premature delivery and other labour complications leading to higher rates of PDs (Fretts 2010, p. 591). Furthermore, the study found that SBRs were 4 times higher in multiple pregnancies than single pregnancies (Fretts 2010, p. 591). In a Tanzanian study, a PNMR of 269 per 1000 births and 118 per 1000 births were found for multiple and single pregnancies respectively with an OR of 2.3 times higher risk in multiple

pregnancies than single pregnancies (Kidanto et al. 2006, p. 74). Similar to labour complications, all multiple pregnancies are managed at secondary or tertiary levels of care.

Gender

The sex of the newborn also has an effect on PNM. Study results, from some areas, have shown that male sex is associated with an increased risk of PNM. The results from an Indonesian study showed that males experienced slightly higher mortality than the females (Titaley 2008, p.15). A descriptive study from Malawi showed a PNMR which was dominated by males- 57.8 percent of perinatal deaths were males (Metaferia & Muula 2009). These findings were different from those obtained in Brazil and Pakistan where it was reported that the sex of the newborn was not associated with mortality (Lanfranchi, Viola & Nascimento 2011, p. 228; Hossain, Khan & Khan 2009, p. 745). No study was found which showed males to have better PNMR than females.

Low birth weight

The survival of newborns is dependent on the BW. There is an inverse relationship between NND and LBW whereby the early neonatal mortality rate (ENNMR) increases with decreasing BW. Babies with a LBW have higher probability of a PD than babies with normal BW. LBW is defined as BW of <2500 grams. Apart from being associated with NND, LBW is also an important indirect cause of ENND. In Zimbabwe, results from two studies, showed that the PNM increases with LBW with an OR of 6.26 times greater risk than normal BW babies (Feresu et al. 2004, p. 157; Emmanuel et al. 2009, p. 5). In South Africa, newborns weighing between 1000g-1499g had a PNMR of 200/1000 births while those weighing ≥ 2500 g had a PNMR of 7/1000 births (ed. Pattinson 2011, p. 58). Therefore, LBW is one of the major risk factors of PNM and it ought to be considered during investigation of PNM risk factors.

Intrapartum hypoxia

Apgar scores are an indication of the infant's need for resuscitation. Newborns that are not resuscitated well are likely to develop the effects of hypoxia which can lead to a PD and other neurological complications. A study in Tanzania reported that 75 percent of neonatal deaths had a 5-minute Apgar score of less than 7 (Kidanto et al. 2006, p. 73). A study in Brazil found that a 5-minute Apgar score of less than 7 was associated with an OR of 5 times greater risk of NND compared to those with a 5 minute Apgar of more than 7 (Lanfranchi et al. 2011, p. 229). In many settings, an Apgar score of 7 and above is considered better because these babies do not develop the effects of intrapartum hypoxia and hence are associated with higher chances of survival than babies with Apgar scores of < 7 . In South Africa, intrapartum hypoxia accounted for about half (48.9%) of SBs and NNDs weighing $\geq 2500\text{g}$ and hypoxia alone contributed 65.2 percent of all NNDs weighing $\geq 2500\text{g}$ (ed. Pattinson 2011, p. 55-56). Deaths from intrapartum hypoxia can be reduced by improving quality of care during labour and immediately after delivery.

2.2.5 Health system factors

PNM is also affected by health system factors. A country with poor health system is more likely to have high PNMR. A Perinatal Problem Identification Programme (PIIP), in South Africa, found that administrative avoidable factors were associated with a PNMR of 2 deaths per 1000 births (ed. Pattinson 2011, p. 20). Health care provider's factors included failure to detect foetal distress, delayed referral and non adherence to basic patient management protocols and guidelines while administrative factors were inadequate facilities, lack of transport and insufficient or inadequately trained health personnel to attend to patients (ed. Pattinson 2009, p. 18). In Western Tanzania, PNM was associated with patient's factors (first level delay),

transportation problems (second level delays) and health related factors (third level delays). Therefore, an improvement in maternal and neonatal health systems in these levels can help to prevent PDs (Mbaruku et al. 2009, p. 85). A case controlled study from Nigeria, observed that delays in purchasing drugs, delays in obtaining drugs for surgery, lack of electricity supply, lack of sterile equipment and delay in the arrival of anaesthetist were the common causes of administrative factors that contributed to PDs (Chigbu et al. 2009, p. 19).

The quality of maternal and neonatal health services also depend on the availability of equipment and supplies. The absence of medical resources and supplies makes it difficult for health providers to offer quality health care (Kholowa 2007, p. 24). In Tanzania, the absence of simple equipment such as Doppler for foetal auscultation, oxygen, and naso-gastric tubes contributed to high PNM (Mbaruku et al. 2009, p. 88). Therefore, availability of drugs, equipment and supplies is critical in the delivery of health services and improvement in these services can lead to better perinatal outcomes in most settings.

Referral and transport system

A good referral system helps the referred patients to reach at the next level of care faster so that clinical management can be carried out in time. However, most countries in Africa have poor referral systems which results into avoidable PDs. In a qualitative study from Tanzania, it was noted that some contributing factors to PDs were delayed referral systems which led to patients taking very long time due to transport problems and this contributed to higher PNMR resulting to a delay in the patient receiving better clinical management (Kidanto 2009, p. 5). In related studies in South Africa, Zimbabwe and Nigeria, it was observed that referred patients had a greater risk of PNM than un-referred patients (Hoque 2011, p. 27; Fawole et al. 2011, p. 40).

This could mean that referred patients have complications or that complications arise during the time that is taken during the act of referring. A good referral system consists of both a good transport system and explicit protocols on patient management outlining which patients need to be referred and when they need to be referred. Therefore, a good referral system is of great importance for the prevention of PNM.

Literature review summary

The literature has found that prematurity, infections, asphyxia and labour complications are some of the major causes of PNM. The review found that PNM was associated with: mother's age, residence, education, occupation, parity, history of a PD, ANC attendance, HIV, gestational age, induction of labour, mode of delivery, labour complications, gender, multiple pregnancy, LBW and health systems factors. All these contribute significantly to high PNMR in studies and reports from different countries.

3.0 Research objectives

3.1 Research questions

1. What is the PNMR and ENNMR among mothers delivering at KCH?
2. What are the causes of ENNDs at KCH?
3. What are some of the socio-demographic factors of the mothers delivering at KCH?
4. What are some of the factors associated with PNMR at KCH?

3.2 Main objective

The main objective of the study is to assess the prevalence and some of the associations of PNM in mothers delivering at KCH between 1st July 2010 and 30th June 2011.

3.3 Specific objectives

1. To determine the PNMR (SBR and ENNMR) for KCH.
2. To determine the causes of ENNDs at KCH.
3. To describe some of the demographic characteristics of mothers delivering at KCH.
4. To explore the associations between some of the maternal, delivery process factors, foetal and neonatal risk factors with PNM

4.0 Research methods

4.1 Study design

The study employed a retrospective study design of a sample of routine programmatic data collected from the patient files. The list of cases was taken from the delivery book in which all deliveries were registered. The details from the case files were compared with those from the delivery book and neonatal admission book in the nursery ward to correct missing values.

4.2 Sample size

The study population was all women delivering at KCH between 1st July 2010 and 30th June 2011.

4.3 Inclusion and exclusion criteria

Cases that were included were: hospital deliveries, birth-weight of equal or more than 1000g, ENNDs and complete information.

Cases that were excluded were: outside hospital deliveries, birth-weight of less than 1000g, LNNDs and incomplete information.

4.4 Study setting and population

The study was conducted at KCH in Lilongwe, which is the largest referral hospital in the central region of Malawi. The study population comprised all deliveries from 1st July 2010 to 30th June 2011 and all these deliveries were sampled for the study. Data for all the SBs were obtained from the patients' files and delivery book while data for the ENNDs were taken from the admission book in nursery ward which also contained the outcome of the newborn.

4.5 Data collection and measurement

Data were extracted from patients files bearing details of patient's demographic data, antenatal care, labour and delivery, and newborn health (see appendix 1). The study was limited to collecting and assessing the data on:

The socio demographic factors: mother's age, residential area, mother's education, mother's occupation and parity.

Antenatal factors: history of SB/NND, referred patient, ANC attendance, HIV status and gestational age at delivery (weeks).

Delivery process: induced labour, mode of delivery, labour complications, sex of newborn and plurality of the foetus.

Newborn health status: BW of newborn, outcome of delivery, Apgar score at 5 minutes, ENND occurrence, days from birth to ENND and cause of ENND.

All case files for the study period were retrieved from the records office. The required information was captured and entered onto a data form. Two data clerks were recruited and were oriented on data collection measures and data was collected over a period of 10 days under the supervision of the researcher. Data were collected from 14 October 2011 to 25 October 2011. After data collection all the information was entered into a computer by a data clerk prior to data analysis.

4.6 Definitions

In this study,

1. *Apgar score* is the score which is given to a newborn at 1 and 5 minutes after birth.

The 5 minute Apgar score was use in this study.

2. *ENND* is defined as death from birth up to and including day 7 and a BW of $\geq 1000\text{g}$.
3. *Intrapartum period* is defined as the period between the onset of labour to delivery.
4. *LNND* is defined as death of the newborn after 7 days of birth till 28 days.
5. *LBW* is defined as BW of less than 2500 grams.
6. *Parity* is defined as the number of times a mother has given birth to a newborn
7. *PD* is defined as the sum of all SBs and ENNDs.
8. *PNMR* is defined as the sum of all PDs in relation to the total births (sum of all SBs and live births). PNMR is calculated as deaths per 1000 births.
9. *Antenatal care* is the care that is given to a pregnant woman from the time that conception is confirmed until the beginning of labour (Fraser, Cooper & Nolte, 2006).
10. *Received antenatal care* in this study is defined as at least 1 attendance at an antenatal clinic. At the clinic each pregnant woman is offered a package of care of iron tablets, intestinal parasites drugs, informed about signs of pregnancy complications, weight recorded, blood pressure measured, urine sample take, blood sample taken and information on which foods to eat (MDHS 2011, p. 106).

4.7 Data management and analysis

Before data analysis, the data capture sheets were assessed for omissions and inconsistency. Data from all data sheets were coded and entered into Microsoft Access 2003 database and analysed using STATA 11.0 software. Descriptive analysis was carried out to determine the perinatal and neonatal mortality rates and to describe the study population. The Pearson's chi-squared test and Fisher's exact tests were used to assess the association between categorical variables (mother's age, residential area, mother's education level, occupation, referral status, history of a PD, ANC

attendance, HIV status, gestation, labour induction, mode of delivery, labour complication, newborn gender, plurality of foetus and Apgar score at 5 minutes) and PNM. The advantage of using chi-square test is that it compares the frequency of cases found in the various categories of one variable across the different categories of another variable (Pallant 2003). Fisher's exact test was used when there were less than 10 observations in each cell.

The variables that were found to be significantly associated with PNM were entered into a univariate and multivariate logistic regression models in order to identify patients' characteristics which were independently associated with the outcome variable. The logistic regression analyses helps to predict a patient's outcome from multiple explanatory variables (Dupont 2002). Stepwise regression method was used to determine the most significant variables or factors in the analysis. The OR were used to describe the strength of association between explanatory variables and outcome variables. All statistical tests were conducted at 95% confidence level. Means, range and standard deviation were calculated for continuous variables. Frequencies and percentages were calculated for categorical variables. Data were presented using frequency tables and histograms.

4.8 Ethical considerations

The study did not expose patients to any risks because it did not directly involve the patients. However, the research proposal underwent a departmental scientific review at the School of Child and Adolescent Health of the University of Cape Town before being reviewed by two ethics committees. Ethics approval was sought by seeking permission from Human Research Ethics Committee of University of Cape Town (HRECUCT) and National Health Sciences Research Committee (NHSRC) in Malawi. The study was also approved by the Director of KCH.

To maintain patient's confidentiality, serial and registration numbers were used on the dataset instead of patient's names. This was in accordance with Helsinki Declaration regarding medical research of the year 2008.

To maintain safety of the charts, a lockable room within the hospital was identified where all the records were kept. Prior to data collection, data clerks were oriented on data collection procedures and on the importance of confidentiality during and after the study. No one was allowed to carry patients' files, or any paper containing patient information, out of the research room other than for the purpose of this study, until the end of the study after which all files were surrendered to the registry for storage. Data were entered on the researcher's personal computer which, at this particular time, was used solely for data entry. Upon completion of data collection, all data sheets were kept safely in the registry until data analysis was finalized and dissertation submitted. All data sheets will be destroyed after publication of the results in a peer reviewed journal and other dissemination fora. The dataset were kept safely in password-protected folders on the researcher's computer incase it may serve as basis for future studies.

4.9 Plans for dissemination of results

When the final report is approved, the results of the study will be presented to the Obstetrics and Gynaecology departmental meeting at KCH and they will also be submitted to a peer review journal for publishing. Copies of the report findings will be forwarded to the Department of Obstetrics and Gynaecology of KCH, NHSRC and the Ministry of Health of Malawi as a potential tool for informing policy decision.

5.0 Findings/Results

5.1 Description of study participants

The retrospective study reviewed data of all the patients who delivered at KCH, one of the tertiary hospitals in Malawi, from July 2010 to June 2011. The data collection was done between 14 October 2011 and 25 October 2011. During the study period the hospital delivered 2307 women. Of these, 13 records were missing while 265 records had inadequate information (on age, residence, education, occupation, parity, referral, history of a PD, ANC attendance, HIV, gestation age, induced labour status, mode of delivery, labour complications, gender of newborn, plurality of foetus, Apgar score and pregnancy outcome). A total of 2294 (99.4%) patients' records/files were analysed for the outcome and to calculate the mortality rates. Of these 2294 records, 2020 (87.6% of total deliveries) were analysed for the factors associated with a PD. Of the 2294 records, 2195 (95%) were live-births while 41 (2%) were MSBs and 58 (3%) were FSBs. Of the live births, 35 (2%) were ENNDs (see **Figure 1** below). The **ENNMR**: 16.9 / 1000 live-births; **SBR**: 43.2 / 1000 births; **PNMR**: 58.4 / 1000 births.

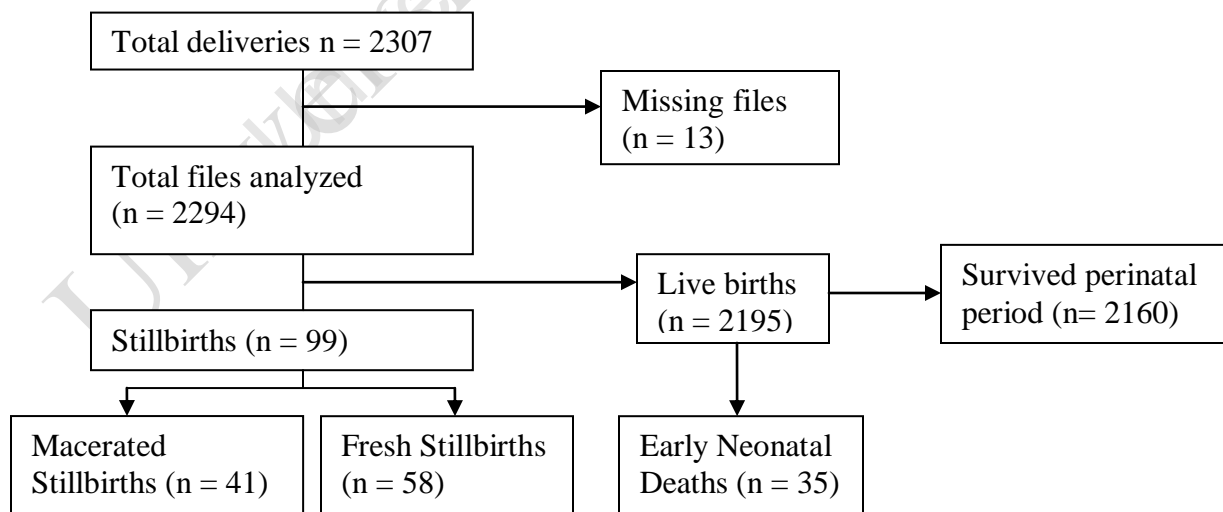


Figure 1: Study population

5.2 Socio-demographic characteristics of women delivering at KCH

Maternal age

There were 1710 (85%) mothers with ages ranging from 20 to 34 years, 179 (9%) were above 34 years while 131 (6%) were less than 20 years. The mothers' ages ranged from 14 to 49 years. The mean age was 27.3 years ($SD=5.2$), with a median age of 32 years, as shown in the **Figure 2** below.

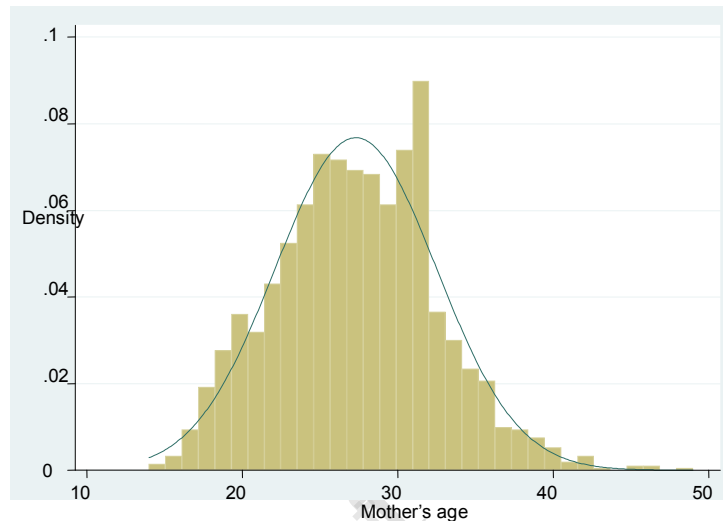


Figure 2: Age distribution of 2020 mothers delivering at KCH from July 2010 to June 2011

Residence: Out of 2020 mothers, 1710 (85%) lived in urban areas, 277 (14%) lived in the rural areas and 33 (1%) lived in semi-urban areas.

Education: 1851 (92%) of women were formally educated while 26 (1%) had no formal education. 143 (7%) had no information on education.

Occupation: 813 (40%) of the women were formally employed while 1116 (55%) were not formally employed. 91 (5%) had no information on occupation.

Parity: 718 (36%) mothers were para one, 550 (27%) were para two, 394 (20%) were para three, 213 (10%) were para four and 145 (7%) were para five and above. Parity ranged from 1 to 14.

Table 1: Socio-demographic factors with comparison of mothers with live births and PDs

Variables	Condition of Newborn		<i>p</i> -value
	Live births (N (%))	Perinatal Deaths (N (%))	
Mother's age (years): <20	115(6.1)	15(12.0)	
20-35	1,658(87.7)	98(78.4)	*0.01 ^c
>35	117(6.2)	12(9.6)	
Place of residence			
Rural	214(11.3)	63(50.4)	
Semi-urban	28(1.5)	5(4.0)	*<0.01 ^f
Urban	1,653(87.3)	57(45.6)	
Mother's level of education			
Educated	1754(99.0)	97(91.5)	*<0.01 ^f
Not educated	17(1.0)	9(8.5)	
Occupation			
Formally employed	786(43.3)	27(23.7)	
Not formally employed	1029(56.7)	87(76.3)	*<0.01 ^c
Parity			
1	686(36.2)	32(25.6)	
2	533(28.1)	17(13.6)	*<0.01 ^c
3	371(19.6)	23(18.4)	
4	194(10.2)	19(15.2)	
5+	111 (5.9)	34(27.2)	

Note: f=fisher's exact test, c=chi square tests, *=statistically significant

Comments on table 1

There was significant association between condition of the baby and mother's age ($p < 0.01$), place of residence ($p < 0.01$), mother's level of education ($p < 0.01$), occupation ($p < 0.01$) and parity ($p < 0.01$).

5.3 Antenatal factors

Previous SB: 1899 (94%) had no history of a SB while 68 (3%) had a history of a SB. 53 (3%) had no information on SB.

Previous NND: 1927 (95%) had no history of a NND while 43 (2%) had a history of NND. 50 (3%) had no information recorded on NND.

Referral status: 366 (18%) were referred from other hospitals and health centers.

Antenatal care: Those who attended ANC, at least once, were 1033 (51%) and 970 (48 %) had unknown ANC status. 17 (1%) did not attend ANC at all. ANC attendance ranged from 0 to 7 visits.

HIV status: HIV positive women were 287 (14%).

Gestation: 448 (22%) had pregnancies < 36 weeks while 1557 (77%) had pregnancies between 37-42 weeks. 4 (< 1%) women had a gestation beyond 42 weeks and 11 (1%) had no information on the gestational period.

Table 2: Antenatal factors with comparison of mothers with live births and PD

Variables	Condition of Newborn		<i>p</i> -value
	Live birth (N (%))	Perinatal Death (N (%))	
SB (history)			
Yes	59 (3.2)	9 (7.4)	
No	1786 (96.8)	113 (92.6)	*0.034 ^f
NND (history)			
Yes	38 (2.1)	5 (4.1)	0.19 ^f
No	1809 (97.9)	118 (95.9)	
Referred			
Yes	283(15.0)	83(66.4)	*<0.01 ^c
No	1,609(85.0)	42(33.6)	
ANC attendance			
Yes	990(98.5)	43(95.6)	0.13 ^f
No	15(1.5)	2(4.4)	
HIV status			
HIV negative	1,567(85.1)	100(89.3)	0.22 ^c
HIV positive	275(14.9)	12(10.7)	
Gestation (weeks)			
28-36 weeks	376 (19.9)	72(58.5)	
37 weeks above	1,510 (80.1)	51(41.5)	*<0.01 ^f

Note: f=fisher's exact test, c=chi square tests, *=statistically significant

Comments on table 2

There was significant association between condition of newborn and stillbirth history ($p = 0.034$), referred patients ($p < 0.01$) and gestation ($p < 0.01$). There was no significant association between condition of newborn and neonatal death history ($p = 0.19$), ANC attendance ($p = 0.13$) and HIV status ($p = 0.22$).

5.4 Delivery process

Induced labour: 236 (11.7%) mothers had induced labour.

Mode of delivery: 1245 (62%) had spontaneous vertex delivery while caesarian sections were 653 (32%), vacuum extractions were 80 (4%) and breech deliveries were 42 (2%).

Complications during delivery: 321 (16%) women had complications during labour of which 75 (23%) had haemorrhage, 47 (15%) had hypertension/preeclampsia, 33 (11%) had ruptured uterus. These 3 conditions made up 48% of all the complications documented. 88 (27%) had cord around the neck, 20 (6%) had obstructed labour and 58 (18%) had other types of complications.

Table 3: Delivery process factors with comparison of mothers with live birth and PD

Variables	Live birth (N (%))	Perinatal Death (N (%))	p-value
Labour induced			
Yes	235(11.8)	1 (3.7)	*<0.01 ^c
No	1758 (88.2)	26 (96.3)	
Mode of delivery			
SVD	1,191(62.9)	54(43.2)	
Breech	31(1.6)	11(8.8)	*<0.01 ^f
V/E	78(4.1)	2(1.6)	
CS	595(31.4)	58(46.4)	
Labour complications			
Yes	247(13.0)	74(59.2)	*<0.01 ^c
No	1,648(87.0)	51(40.8)	

Note: f=fisher's exact test, c= chi square test, *=statistically significant

Comments on Table 3

There was significant association between condition of newborn and induction of labour ($p < 0.01$), mode of delivery ($p < 0.01$) and labour complications ($p < 0.01$).

5.5 Neonatal and perinatal mortality

Birth weight: 1860 (81%) of the new born babies had a birth weight of 2500g and above, 225 (10%) had a birth weight between 2000g and 2499g, 126 (5%) had a birth weight between 1500g and 1999g while 83 (4%) had birth weight between 1000g and 1499g. Birth weights were normally distributed with a mean of 2934.4g (SD= 664.2).

Outcome:

- Of the 83 babies weighing between 1000 - 1499g 58 (70%) were live births, 18 (22%) were MSB, 7 (8%) were FSB. Among the live births 16 (23%) were ENNDs.
- Of those weighing between 1500 - 1999g 114 (90%) were live births, 4 (3%) were MSB and 8 (6%) were FSB. Of the live births 4 (3%) were ENN Ds.
- Of those weighing between 2000 - 2499g 209 (93%) were live births, 7 (3%) were MSB and 9 (4%) were FSB. Of the live births 3 (1%) were ENNDs.
- Of those weighing 2500g and above 1814 (98%) were live births, 12 (1%) were MSB and 34 (2%) were FSB. Of the live births 12 (1%) were ENNDs. See **Table 4** below.
- The mortality rates for the birth weight categories are shown in **Table 5**

Table 4: Comparison of birth weight, early neonatal mortality and perinatal mortality

Birth weight	Total deliveries	Live births	MSB	FSB	ENND
1000 - 1499g	83	58	18	7	16
1500 - 1999g	126	114	4	8	4
2000 - 2499g	225	209	7	9	3
2500g +	1860	1814	12	34	12
Total	2294	2195	41	58	35

Table 5: Comparison of SBR, ENNMR and PNMR

Birth weight	SBR/ 1000 births	ENNMR / 1000 live births	PNMR / 1000 births
1000 - 1499g	301.2	275.8	494.0
1500 - 1999g	95.2	35.1	127.0
2000 - 2499g	71.1	14.4	84.4
2500g +	24.9	6.6	31.4
Total	43.2	15.9	58.4

Sex of babies: Male babies were 1013 (50.1%) and females were 1007 (49.89%).

Multiple pregnancy: 1925 (95%) were singleton babies while 92 (5%) were twin deliveries. 3 (< 1%) babies were triplets (1 set).

Apgar score (at 5 minutes): 1887 (98%) of babies had good Apgar score of 7 and above. 30 babies (2%) had Apgar score of 4 – 6 while 7 (< 1%) had an Apgar score of 1 - 3.

Early neonatal deaths: Among the ENNDs 16 (55%) died on the first day of life and 5 (17%) died on second day of life.

Causes of early neonatal death: 20 (57.6%) of the ENNDs were caused by prematurity, followed by 10 (28.6%) caused by birth asphyxia and 3 (8.6%) were caused by CAs.

Table 6: Comparison of newborns health and PD

Variables	Live births (N(%))	Perinatal Deaths(N(%))	p-value
Birth weight(g)			
1000-1499g	43(2.0)	40(30.1)	
1500-2499g	316(14.6)	35(26.3)	*<0.01 ^c
2500g and above	1,802(83.4)	58(43.6)	
Sex of the new born			
Female	947(50.0)	57(46.7)	0.49 ^c
Male	948(50.0)	65(53.3)	
Plurality of fetus			
Singleton	1,809 (95.5)	116(92.8)	0.31 ^f
Twins	83(4.4)	9(7.2)	
Triplets	3(0.2)	0(0)	
Apgar score			
1-3	1(0.1)	6(20.7)	
4-6	22(1.2)	8(27.6)	*<0.01 ^f
7+	1,872(98.8)	15(51.7)	

Note: ^f= fisher's exact test, ^c=chi square tests, *=statistically significant, the denominator for BWT was 2294 deliveries

Comments on Table 6

There was significant association between condition of newborn and birth weight ($p < 0.01$) and Apgar score ($p < 0.01$). However, there was no association between condition of the newborn and sex of the newborn ($p = 0.49$) and plurality of foetus ($p = 0.31$).

5.6 Univariate and Multivariate analyses

Where the variable in tables 1, 2, 3, and 6, showed a statistically significant difference, it was subjected to univariate and multivariate logistic regression analyses in-order to obtain ORs and *p*-values. The OR helps to describe the strength of the association between the exposure and the outcome. The results are shown in **Table 7** below.

Table 7: Univariate and Multivariate Logistic Regression with OR and 95% Confidence Interval (95%CI) for perinatal deaths at KCH

Characteristics	Unadjusted		Adjusted	
	OR (95 % CI)	<i>p</i> -value	OR (95 % CI)	<i>p</i> -value
Mother's age				
<20	2.11(1.19-3.75)	0.01*	2.11(0.56-7.88)	0.27
20-35	1		1	
>35	1.74(0.93-3.25)	0.09	0.18(0.01- 5.70)	0.33
Place of residence				
Rural	8.54(5.81-12.55)	<0.01*	3.17(1.00-10.02)	0.05*
Semi-urban	5.18(1.93-13.90)	<0.01*	22.83(4.40-118.45)	<0.01*
Urban	1		1	
Maternal education				
Formally educated	0.11 (0.5-0.24)	<0.01*	1.26 (0.10-16.45)	0.11
Not formally educated	1		1	
Maternal occupation				
Formally employed	0.41 (0.26- 0.63)	<0.01*	0.10 (0.39-2.32)	0.92
Not formally employed	1		1	
Parity				
1	1		1	
2	0.68 (0.38-1.25)	0.21	0.20 (0.04-0.92)	0.04*
3	1.34 (0.77-2.31)	0.31	1.35(0.42-4.34)	0.61
4	2.10 (1.16-3.79)	0.01*	0.83(0.15-4.51)	0.83
5 +	6.63 (3.93-11.18)	<0.01*	5.51(1.54-19.68)	<0.01*
SB history				
Yes	2.41 (1.17-4.99)	0.018*	1.07 (0.06-20.33)	0.97
No	1		1	
Referred mothers				
Yes	11.23(7.59-16.62)	<0.01*	0.82(0.27-2.52)	0.73
No	1		1	
Gestational age				
28-36	1		1	
37 +	0.18 (0.12-0.26)	<0.01*	2.00 (0.34-11.69)	0.44

Labour induced				
Yes	1.68(1.04-2.72)	0.03*	4.28(0.22-82.10)	0.34
No	1		1	
Mode of delivery				
SVD	1		1	
Breech	7.81 (3.73-16.40)	<0.01*	5.30 (2.16-13.0)	<0.01*
V/E	0.57 (0.14-2.36)	0.44	0.42(0.09-1.97)	0.272
C/S	2.15(1.47-3.16)	<0.01*	1.80(1.15-2.81)	0.01*
Complications of labour				
Yes	9.68(6.61-14.17)	<0.01*	1.74(0.60- 5.10)	0.31
No	1		1	
BW(g)				
1000-1499	25.82(15.28-43.63)	<0.01*	14.87(4.45-49.77)	<0.01*
1500-2499	3.19(2.01-5.07)	<0.01*	1.73(0.54-5.60)	0.36
2500 and above	1		1	
Apgar score at 5 minutes				
1-3	16.49(1.71-159.13)	0.02*	23.09(1.62-329.97)	0.02*
4-6	1		1	
7+	0.02 (0.01-0.06)	<0.01*	0.04(0.01-0.15)	<0.01*

Note *=statistically significant
1= Referent category

Comments on Table 7

In the **Univariate logistic regression analysis**, mother's age, place of residence, mother's education, mother's occupation, parity, history of SB, referred mothers, gestational age, induced labour, mode of delivery, labour complications, birth weight and Apgar score were significantly associated with PDs.

Maternal age: Babies born to mothers whose ages were below 20 years had a higher risk of dying than those whose mothers were aged between 20 and 35 years (mother's age < 20: OR: 2.11, 95 % CI: 1.19-3.75). In mother's age > 35 there was no association found compared to those aged between 20 and 35 years (OR: 1.74, 95 % CI: 0.93-3.25).

Place of residence: Babies whose mothers were staying in the rural and semi urban areas were more likely to die than those babies whose mothers were staying in urban areas (rural: OR : 8.54, 95 % CI: 5.81-12.55, semi-urban: OR: 5.18, 95 % CI:1.93-13.90).

Mother's education: Babies born to mothers with formal education were less likely to die than babies born to mothers without formal education (OR: 0.11, 95% CI: 0.05-0.24).

Mother's occupation: Babies born to mothers who were formally employed were less likely to die than babies born to mothers without formal employment (OR: 0.41, 95% CI: 0.26-0.63).

Parity: Babies born to mothers with parity of four and five were more likely to die than babies born to mothers with parity of one (parity four: OR: 2.10, 95% CI: 1.16-3.79, parity five: OR: 6.63, 95% CI: 3.93-11.18). In babies born to mothers with parity of two and three there was no significant association compared to babies born to mothers with parity of one (parity two: OR: 0.68, 95% CI: 0.38-1.25, parity three: OR: 1.34, 95% CI: 0.77-2.31).

Stillbirth history: Babies born to mothers with previous history of a SB were more likely to have a PD than those born to mothers without history of a SB (OR: 2.41, 95% CI: 1.17-4.99).

Referred mothers: Babies born to mothers who were referred from other health centres had a higher probability of dying than those babies whose mothers has originally reported the facility under study (OR: 11.23, 95 % CI: 7.59-16.62).

Gestational age: Babies born to mothers with gestational age of 37 and above were less likely to die than babies born to mothers with gestational age of between 28 and 36 weeks (OR: 0.18, 95% CI: 0.12-0.26)

Induced labour: Babies to mothers who had labour induction were more likely to die than babies born to mothers without labour induction (OR: 1.68, 95% CI: 1.04-2.72).

Mode of delivery: Babies born through breech and C/S deliveries were more likely to die than babies born through SVD (breech: OR: 7.81, 95% CI: 3.73-16.40, C/S: OR: 2.15, 95% CI: 1.47-3.16). Babies born through V/E were unlikely to die compared to SVDs (OR: 0.57, 95% CI: 0.14-2.36)

Complications of labour: Babies born to mothers who had labour complications had a higher probability of dying than those babies whose mothers had no labour complications (OR: 9.68, 95 % CI: 6.61-14.17).

Birth weight: Babies with BW between 1000g and 1499g and those with BW between 1500g and 2499g were more likely to die than babies whose BW were 2500g and above (BW 1000g - 1499g: OR: 25.82, 95 % CI: 15.28-43.63, BW 1500-2499g: OR: 3.19, 95 % CI: 2.01-5.07).

Apgar score (at 5 minutes): Babies with an Apgar score of 1 - 3 had a higher probability of dying than those babies with a 5-minute Apgar score of 4-6 (OR: 16.49, 95 % CI: 1.71-159.13) and babies with a 5-minute Apgar score of 7+ had a lower probability of dying than those babies with an Apgar score at 5-minute of 4 - 6 (OR: 0.02, 95 % CI: 0.01-0.06).

In the **Multivariate logistic regression analysis**, place of residence, parity, mode of delivery, birth-weight and a 5-minute Apgar score were significantly associated with PDs. However, there was no association between a PD and mother's age, mother's education, mother's occupation, being referred, having history of a SB, gestational age, induced labour and labour complications.

Place of residence: Babies whose mothers were staying in the semi urban areas had a higher probability of dying than those babies whose mothers were staying in the urban (adjusted OR: 22.83, 95 % CI: 4.40-118.45). No statistically significant association was found between rural mothers and urban mothers (adjusted OR: 3.17, 95 % CI: 1.00-10.02).

Parity: Babies born to mothers with parity of 2 were unlikely to die than babies born to mothers with parity of 1 and babies born to mothers with parity of 5 and above were more likely to die compared with those born to mothers with parity of 1 (parity 2: adjusted OR: 0.20, 95% CI: 0.04-0.92, parity 5: adjusted OR: 5.51, 95% CI: 1.54-19.68). There was no statistically significant

association between babies born to mothers with parity of 3 and 4 compared to those born to mothers with parity of 1 (parity 3: adjusted OR: 1.35, 95% CI: 0.42-4.34, parity 4: adjusted OR: 0.83, 95% CI: 0.15-4.51).

Mode of delivery: Babies who were born through breech delivery and C/S were more likely to die than babies born through SVD (breech: adjusted OR: 5.30, 95% CI: 2.16-13.0, C/S: adjusted OR: 1.80, 95% CI: 1.15-2.81). No significant association was found between babies born through V/E and those born through SVD (V/E: adjusted OR: 0.42, 95% CI: 0.09-1.97).

Birth weight: Babies with BW between 1000g and 1499g were more likely to die than those babies whose BW were 2500g and above (BW 1500g-1499g: adjusted OR: 14.87, 95 % CI: 4.45-49.77). There was no statistically significant association between babies with BW 1500g-2499g and 2500 and above (adjusted OR: 1.73, 95 % CI: 0.54-5.60).

Apgar score: Babies with a 5-minutes Apgar score of 1 - 3 had a higher probability of dying than those babies with a 5-minute Apgar score of 4 - 6 (adjusted OR: 23.09, 95 % CI: 1.62-329.97) and babies with a 5-minute Apgar score of 7+ had lower probability of dying than those babies with a 5-minute Apgar score of 4 - 6 (adjusted OR: 0.04, 95 % CI: 0.01- 0.15).

6.0 Discussion

The study was undertaken at KCH to:

1. Determine the SBR, ENNMR and PNMR at KCH
2. Determine the causes of ENNDs
3. Describe some of the socio-demographic characteristics of women delivering at KCH
4. Explore some of the associations between maternal, delivery process factors, fetal and neonatal risk factors with PNM

6.1 Mortality data at Kamuzu Central Hospital

6.1.1 Perinatal mortality rates

The study results showed that in the 2294 patients, with a baby weighing $\geq 1000\text{g}$ at birth, whose data were available, the SBR was 43.2 deaths per 1000 births; the ENNMR was 15.9 per 1000 live births giving a PNMR of 58.4 per 1000 births. The PNMR in Mangochi, a rural area in southern Malawi, was 68/1000 births (McDemott et al. 1996, p. 167). In the study done in a referral hospital in Blantyre by Muula & Metaferia (2009) showed a PNMR of 79/1000 births for babies weighing $\geq 500\text{g}$ at birth, and a study at Muhimbili National Hospital, Dar es Salaam showed a PNMR of 124/1000 births (Kidanto et al. 2006, p. 75). In both studies, from Tanzania and Blantyre, the inclusion criteria were a BWT of $\geq 500\text{g}$ while in this study it was $\geq 1000\text{g}$. In Mangochi study gestation age of 28 weeks and above was used instead of BWT. The unusual higher PNMR for a population based study in Mangochi than in a referral hospital-based study at KCH could be attributed to compromised quality of health care in community health facilities in Mangochi which made pregnant mothers not to access the facilities. A study in Tanzania showed that referral hospitals are more likely to have higher PNMRs than community-based surveys (Mbaruku et al. 2008, p. 85). However, the rate at KCH is higher than a reported national rate of

40 per 1000 births (MDHS 2010, p. 100). The National PNMR in South Africa for 2008 – 2009 was 28/1000 births for infants with a birth weight of 1000g or more (ed. Pattinson 2011, p. 45). This was a facility based study, but was undertaken in all levels of care. This shows that it should be possible to improve the perinatal outcomes at KCH despite South African health services being better developed than in Malawi.

6.1.2 Early neonatal mortality rates at KCH

The ENNMR at KCH in the study period was 15.9/1000 live births. The other studies in Malawi did not document this rate possibly because there is no segregation of data for ENNDs and LNNDs in Malawian data. The ENNMR is a marker of the quality of the care given to newborn babies. However, 10 years data from South Africa (ed. Pattinson, 2011, p. 53) gives an ENNMR of 8.5/1000 live births for all facilities and about 10/1000 live births for tertiary facilities. While the South African Health Service is probably better resourced than that in Malawi, these figures do give a target which can be aimed at. This mortality figure shows that there needs to be an improvement in newborn care at KCH. Surprisingly, ENNMR from this study was lower than rates from Nigeria and Central African Republic and almost half the average ENNMR for developing countries (Oji 2008, p. 32; Engmann et al. 2009, p. 115; WHO 2006, p. 51). The difference could be explained by the differences in the target population. This study was a hospital based while other studies were community or population based studies.

6.1.3 Causes of Early neonatal mortality

The leading causes of ENND in this study were found to be prematurity (57.1%), birth asphyxia (28.6%) and CAs (8.6%). Half of the ENNDs occurred on the first day after delivery and 14 percent occurred on the second day. This means that nearly two thirds of the deaths occurred in

the first 2 days of life. This suggests that the quality of care during this time period may not be as good as it should be. However, there is not much that can be done for babies with severe birth asphyxia who may also die in this period. This trend is similar to results of studies in Tanzania and Delhi (Kidanto et al. 2006, p. 75; Sinha 2006, p. 189). In South Africa, 36 percent of ENNDs are caused by Asphyxia and 29 percent by prematurity (ed. Pattinson 2011, p. 29). The high number of premature infants could be due to many complicated obstetric cases and preterm labour. These problems trigger early births thereby increasing the risk of prematurity. This finding emphasizes the need to improve the quality of newborn care in the hospital.

BA was responsible for 21 percent of ENNDs. In South Africa and Tanzania, BA contributed 30 percent and 37 percent of ENNDs respectively (Kidanto et al. 2006, p. 80; ed. Pattinson 2011, p. 31-32). However this needs to be looked at in the context of the ENNMR. However it is clear that in the context of the African studies that BA is a serious problem and that it needs to be addressed if the mortality rates are to be reduced.

CAs contributed about 7 percent of ENNDs. This rate was similar to South Africa where CAs caused 7.4 percent of ENND (ed. Pattinson 2011, p. 31-32). It is expected that CAs have an increased association with mortality, as some of them are incompatible with life. Others require highly specialized medical personnel and sophisticated equipment which are not available at the hospital. This leaves these children with only one option which is death.

In a report on Africa's newborns, it was shown that the main causes of neonatal death were documented as: Infections (39%), preterm (25%), asphyxia (24%) and congenital abnormalities (6%) (eds. Lawn & Kerber 2006, p. 14). It is noteworthy that infections did not appear significantly in the causes of death at KCH. It is possible that infection was not being recognised as a cause of death. This needs to be looked at critically.

6.1.4 Stillbirth rate

The SBR, in the present study, was 43.2/1000 births. This rate is higher than 31 deaths per 1000 births which is the WHO estimated rate for least developed countries (WHO 2006, p. 18) but is lower than the findings from Ethiopia and Pakistan (Shamshad 2010, p. 167; Korejo et al. 2007, p. 168). In the present study, it was observed that most SBs were caused by ruptured uterus (44%), APH (19%), intrapartum asphyxia (14%) and hypertension (11%). A tertiary hospital in South Africa found a SBR of 23.4/1000 births and common causes were maternal hypertension, APH and intrapartum asphyxia (Pattinson 2011, p. 99). The main contributing factor to FSBs is failure to recognize fetal heart problem in labour and this is a possibility at KCH.

6.2 Socio-demographic factors and perinatal mortality

Maternal age

In this study maternal age, of less than 20 years was found to be significantly associated with PNM compared with the age group of 20 to 35 years (OR: 2.11, 95% CI: 1.19 - 3.75). However, when adjusted for other variables, it lost its significance. Women more than 35 years were not significantly associated with PNM in the univariable logistic regression analysis (OR: 1.74, 95 % CI: 0.93-3.25). The results are different from those obtained from Brazil, Zimbabwe, Nigeria and regional reviews for developing countries where it was found that maternal age less than 20 and more than 35 years were associated with a higher risk of PNM (McLure, Nalubamba-Phiri & Goldenberg 2006, p.84; Romero-Gutierrez et al. 2005, p. 4; Feresu et al. 2005, p. 4; Fawole et al. 2011, p. 38). In India and South Africa, maternal age and PNM relationship was found to be “U” shaped with age extremes having higher PNM (Checkol 2011, p. 15; Pattinson 2011, p. 9). Although not statistically significant, there were proportionally more perinatal deaths in the mothers older than 34 years. It is possible that this difference could have become statistically

significant if there had been greater numbers in the study. Women less than 20 years have inadequate knowledge on newborn care and have a risk of delayed labour progress of labour and complications such as eclampsia while women more than 35 years can develop labour complications such as cephalo-pelvic disproportion and uterine rupture. All these problems increase the risk of labour complications which in-turn increases PDs.

Residential area

The study found that mothers who lived in semi-urban and rural areas had a 5.2 and 3.2 fold greater risks of a PD than mothers from urban areas respectively. These results are similar to those found in Zimbabwe where it was found that mothers who lived in rural and semi-urban areas had a 3.3 fold greater risk of a PD compared to mothers from urban areas (Emmanuel et al. 2011, p. 5). Mothers from rural areas have greater risk of a PD than urban mothers because most of the times they have poor socioeconomic status and they often have delays in seeking access to quality maternal health services, and also have problems with getting to a health care facility. Mothers with better access to maternal health services are likely to have a lower risk of PNM than mothers with poor access to maternal health services (Emmanuel et al. 2011, p. 5). This may be due to cultural reasons, distance from the health care facility and poor transport, especially at night. A study from Uganda (Nankabirwa et al. 2011, p. 5) showed a better outcome for rural women than for urban women. However, the study design had a bias in the selection of the rural patients, hence such results cannot be generalised.

Maternal education

In this study, education was not significantly associated with a PD. These findings are different from those reported in a Tanzanian study and a systematic review study for developing countries

where it was found that women without formal education had a higher risk of a PD than those with formal education (McLure, Nalubamba-Phiri & Goldenberg 2006, p. 85; Habib et al. 2008, p. 961). Educational level can also affect woman's reproductive behavior and increases her skill in health care practices such as contraceptive use, nutrition, hygiene, and preventive care and disease treatment and it is used as a proxy measure for socioeconomic status (Chekol 2011, p. 15; Seckin 2009, p.13). In contrast, women without formal education are likely to have limited finances and, in the context of Malawi, they are less likely to ably make an independent decision on their own without the husband especially when they are in labour and this put them at greater risk of death (Kholowa 2007, p. 19).

Occupation

The study did not find any statistically significant association between occupation and a PD. These findings are similar to those from Ethiopia where it was noted that unemployed mothers had a greater risk of PDs compared to employed mothers but these results were not statistically significant (Chekol 2011, p. 13). A study in Indonesia found that employed mothers had a greater risk of a PD as compared to unemployed mothers (Titaley et al. 2008, p.11). It is a known fact that unemployed mothers are able to care for their newborns better than employed mothers who spend most of their time at work. The lack of statistically significant association between occupation and a PD in this study could be related to the fact that most of the mothers were from town therefore they were more likely to be economically stable probably due to paternal involvement in employment or business.

Parity

The present study showed that mothers with parity of 5 and above were more likely to have a PD than primiparous women. These findings are similar to those from Nigeria and Zimbabwe where

parity of ≥ 5 was associated with higher PNM (Fawole et al. 2011, p. 39; Emmanuel et al. 2011, p. 5). Complications during pregnancy, labour, and after delivery are found more frequently in grandmultiparous women (Shahid & Mamoon 2009). Mothers with increased parity experience more complications due to laxity of the uterus which comes as a result of frequent pregnancies. The study found that a parity of 2 was associated with a lower risk of PNM compared to parity 1. This was an expected finding because parity of 2 is considered to have a lower risk for a PD. Parity 1 is considered a risk factor for PDs because it can be associated with delayed labour progress which can lead to labour complications like foetal asphyxia. This is why pregnant mothers in these risk categories have to be delivered at a hospital where BEmOC services are present.

6.3 Antenatal factors

Antenatal attendance

In this study, at least one attendance at an ANC was found not to be associated with PNM. Two studies from Central Africa and Zimbabwe found a double higher risk of a PD in mothers who did not attend ANC (Engmann et al. 2009, p. 116; Feresu et al. 2005, p. 7). Mothers attending ANC undergo pregnancy monitoring which enables early detection and treatment of complications, nutrient supplementation, birth preparedness and disease prevention (MDHS 2010, p. 103). This package helps ANC mothers to have better knowledge and usage of maternal health services than mothers without ANC.

However, ANC is more than just an attendance at a clinic. It is the means for detecting problems so that the mother and baby will have the best possible outcome. While one attendance for ANC has been shown to make a difference to the outcome, the aim is to have several visits at critical times for problem detection. The fact that one visit for ANC makes a difference may be an

indicator of other factors in the mother and her environment compared with those who do not attend at all. The fact that, in this study, no difference was found may be related to the small numbers of patients who had not received antenatal care. However, there was poor documentation of this variable in patients' files which was evidenced by 48 percent of patients who did not have documentation on ANC attendance.

History of perinatal death

In the current study it was found that a history of a PD was not significantly associated with a PD after controlling for confounders. In Zimbabwe, a history of SB and ENND increased the risk of PNMR by 4 fold and 7 fold respectively (Emmanuel et al. 2009, p. 5). A maternal history of a PD can be associated with a PD in a subsequent pregnancy and this can be prevented by good history taking as this provides direction on the management of patients. In this study, there was no association found between a previous PD and an adverse outcome in the present pregnancy. It is possible that there were insufficient numbers to be able to demonstrate a difference. It was uncertain from the records whether this information was always requested from the patients at the antenatal clinic visits. This is an issue of possible substandard documentation which is one of the findings of the study, and which needs to be addressed.

Referred patients

Women who were referred from rural and semi-urban areas had a 11.2 times greater risk of a PD than un-referred patients but this became statistically insignificant on Multivariate Logistic Regression. In a related study from Nigeria found that referred women had almost a 2 fold increased chance of a PD than un-referred women (Fawole et al. 2011, p. 40). There are two issues relating to referred patients. Firstly there is the reason for referral. The patients are usually referred because there is a problem and therefore are already at an increased risk of an adverse

outcome of the pregnancy and labour. Secondly there is the issue of the distance which they may have to travel to get to the referral hospital, and the availability of suitable transport, which has similar considerations to those discussed above under “Place of Residence”.

Maternal HIV infection

This study found that Maternal HIV infection was not associated with an increased risk of PNM in this study. Similar findings were obtained in Zambia (Stringer et al. 2011, p. 1156). However, a study in Zimbabwe, found a 5.36 fold increased risk of PNM in HIV infected mothers compared to non HIV infected mothers (Emmanuel et al. 2011, p. 5). Although maternal HIV infection is known to compromise maternal immunity, its effect on ENND is minimal. The evidence is that maternal HIV infection does not affect the early neonatal mortality but is, in South Africa, the main factor associated with deaths in older children – 35 percent of deaths are HIV/AIDS related (ed. Pattinson 2008, p. 1298). However, in Malawi, HIV infected mothers are put on ART to improve the health status of the mother and in-turn increasing the survival of newborns.

Gestational age

Babies born to mothers with gestational age of less than 36 weeks are at greater risk of a PD compared to those with gestational age of 37 weeks and above. These preterm pregnancies deliver preterm babies as well thereby risking them to neonatal problems like immaturity and its complications and infections. The present study did not find an association between gestational age and a PD in the multivariate analysis. This finding was different from that obtained from Zimbabwe and Pakistan where it was noted that preterm delivery increased the risk of a PD compared to term deliveries (Feresu et al. 2004, p. 158; Marchant et al. 2012, p. 1).

6.4 Delivery process

Induced labour

The study found no association between a PD and induced labour in the multivariate analysis. In Tanzania, induced labour was associated with a PD because of high dose of oxytocic drugs and poor monitoring which increased the risk of asphyxiated babies (Kidanto et al. 2009, p. 5). Induced labour can cause hyper-stimulation of the uterus which also affects maternal-foetal oxygen supply thereby increasing the risk of foetal death. On the contrary, a systematic review found that induction of labour was protective against PDs in pregnancies from 41 weeks and above (Hussain et al. 2011, p. 4). This shows that induction of labour could be a problem mainly in areas where foetal monitoring is compromised.

Mode of delivery

The study found a statistically significant association between a PD and mode of delivery. Babies born through breech delivery had 5.3 times greater risk of death compared to those born through SVD. These findings are consistent with those obtained from Zambia and London where ORs of 6.6 and 4.5 were found in London and Zambia (Stringer et al. 2011, p. 1156; Smeeton 2004, p. 5). Breech delivery is associated with other problems like stuck head and cord prolapse which causes foetal hypoxia and foetal death.

CS delivery was also found to be significantly associated with a PD with an OR of 1.8 compared to SVD deliveries. In London, emergency CSs were associated with a 19.4 times greater risk of SBs (Smeeton et al. 2004, p. 4). A study from Kathmandu Medical College, in Nepal, it was found that CS contributed about 31.3% of PDs (Shrestha et al. 2006, p. 178). However, CS alone is not a risk factor for PDs but it becomes a risk factor when it is associated with other labour complications which most of the time would require CS. In some complications like eclampsia,

CS is performed to save the life of the mother. This evidence also shows that KCH, being a referral hospital, performs CS on dead fetuses or severely asphyxiated babies that die soon after delivery.

Complications in labour

Women with labour complications had a 9.7 fold greater risk of having a PD than those without complications ($P < 0.01$). But this became not statistically significant in the multivariable analysis. The most common labour complications in the study were cord around the neck (28%), haemorrhage (24%), hypertension (11%) and ruptured uterus (22%). These complications are likely to cause foetal distress (foetal hypoxia) which can subsequently lead to a PD. This finding is similar to other studies done elsewhere which showed that complications, both maternal disease and labour related, such as cord prolapse, malpresentation, antepartum haemorrhage (APH) and preeclampsia were associated with PNM (Emmanuel et al. 2011, p. 5; Titaley et al. 2008, p. 13). This shows that labour complications are important associations with perinatal mortality. Some of these complications are preventable while others can be treated early to reduce the effect on the fetus. However, for some of the complications, such as abruptio placentae, there is often little that can be done.

The findings are not surprising, as those women with complications during labour can be expected to have a poorer outcome. The challenge is to be able to identify them early enough to be able to manage them quickly and correctly. It is clear from this data that the details of what is happening in the labour ward in this hospital need to be looked into carefully with a view to setting up appropriate management strategies.

6.5 Foetal factors and their association with perinatal mortality

Gender of infant

In this study the sex of the newborn was not associated with PD ($p < 0.49$) and this is inline with some previous studies. In studies conducted in Pakistan and Brazil, it was observed that sex of the newborn was not associated with a difference in PD rates (Hossain et al. 2009, p. 745; Lanfranchi et al. 2010, p. 288). However, a study in South Africa showed that the sex of the newborn was related to PNM. In that study it was reported that boys had higher risk of neonatal mortality (OR: 1.63, 95% CI: 1.13-2.36) (Hoque, Haaq & Islam 2011, p. 28). It was concluded from the above study that boys had a slightly higher risk of ENND than girls. Male neonates are said to be biologically vulnerable to deaths than female neonates (Hoque, Haaq & Islam 2011, p. 28). However, a practical point of view, this will not affect the management of the baby.

Apgar score

In this study, 5 minute Apgar scores of 1-3 were associated with a 23.1 higher risk for PDs than with Apgar scores of 4 - 6 on a multivariable analysis. A 5 minute Apgar score of 7 and above was associated with a low risk of ENND (OR: 0.04 95% CI: 0.01 - 0.15, $p < 0.02$). These findings are similar to a previous cited study done in Brazil which found that 5-minute Apgar score of less than 7 was associated with a 5.3 times higher risk of having a PD (RR: 5.3, 95% CI: 1.57 - 17.5, $p = 0.007$) (Lanfranch et al. 2010, p. 227). Apgar scores are used to detect the need for resuscitation soon after birth of the newborn. A 5 minute Apgar score is an indication of the success or failure of resuscitation.

The main reason for a baby requiring resuscitation is that it is not breathing. A good Apgar score at 5 minutes is therefore an indication that the baby is probably breathing well and spontaneously. A baby who is not breathing well is therefore likely to have a depressed

respiratory centre, either due to immaturity (preterm labour related) or to hypoxic damage occurring during labour, usually in term or near term babies. It is therefore not surprising that the babies with a low Apgar score at 5 minutes have a significantly poorer neonatal outcome. This finding raises the practical need for fetal hypoxia during labour to be recognised and managed, and the need for all staff working in the delivery area to be able to efficiently resuscitate a newborn baby.

Low birth weight

LBW is associated with PNM especially in developing countries. The mean birth weight for all newborns in this study was 2934.4g (SD=664.2) and a LBW prevalence of 19%. This mean birth weight was higher than what was reported in the Blantyre study but it was lower than in Vietnam. In the Blantyre study, it was found that the mean birth weight was 2155g (SD= 938) (Metaferia & Muula 2009, p. 2). This is an unusually low mean birth weight, as in most populations, the mean birth weight is about 3000g. In Vietnam, Graner et al. (2010), a mean birth weight of 3112g (SD = 435) with a low birth weight prevalence of 5.0% were obtained from a population based study. This study shows a higher LBW prevalence at KCH than in Vietnam. The high prevalence of LBW at KCH could have contributed to the lower mean birth weight than the one obtained in Vietnam.

In this study, it was further found that birth weight of 1000 - 1499g was highly associated (14.9 times) with a risk of PD when compared with birth weight of 2500g and above in the multivariable logistic regression analysis. These findings are similar to a retrospective data review study in Brazil where LBW of < 1500g was associated with a higher risk of neonatal death than birth weight of > 1500g (RR: 10.98 95% CI: 3.57 - 33.17, $p < 0.001$) (Lanfranch et al. 2010, p. 227). The mortality in these small babies is a reflection of the quality of newborn care

provided in the institution. In the South African Saving Babies Report, 2008 – 2009 (ed. Pattinson 2011, p 46), it is clear that the mortality rates for babies weighing less than 1500g at birth have a much worse outcome than those weighing 1500g or more.

Plurality of foetus

The study did not find any association between PNM and number of foetuses in the uterus despite other studies finding different results. In the present study, multiple pregnancies accounted for about 5 percent of total deliveries. This rate was lower than the rate of 13 percent which was obtained at QECH by Metaferia and Muula (2009). This low prevalence of multiple pregnancy could explain the lack of association between the two. Multiple pregnancy is usually associated with preterm labour which is also a risk factor for PNM. It was for this reason that some of the reviewed studies had to exclude mothers with multiple pregnancies from their studies.

Limitations of the study

- It was a retrospective case review study. The findings are therefore mainly dependant upon the recording in the patients' case notes.
- The documentation in the case files was not up to standard. This was a key finding of the study. However, 87.6% of the case notes had sufficient information to be able to get reliable data, and it was possible to get birth weight, perinatal outcome and cause of death in 99.4% of the patients who delivered during the study period.
- In retrospect, it became clear that there were important aspects of patient care which should have been included. For a number of practical reasons this could not be done once it became evident.

- The study results might not reflect an accurate record of PNM for the district because it analysed only hospital-based deliveries thereby ignoring deliveries that took place outside the hospital. Furthermore, KCH is the referral hospital for the central region of Malawi. Therefore, the results are a reflection of both patients referred from other districts and those within Lilongwe.

Summary of the discussion

The study found that BWT between 1000 and 1499g, rural and semi-urban residence and low 5 minutes Apgar score (1-3), parity greater than 5 and breech and CS delivery were significantly associated with PNM. Parity of 2 and a 5 minutes Apgar score from 7 and above was protective factor against PNM. Improved management of mothers and babies with these problems will likely improve maternal and neonatal health care thereby preventing PDs at the hospital and surrounding health facilities.

This study only reports on the findings of 1 year's deliveries. The numbers were quite small, and with greater numbers, it is possible that some of the other associations may have become significant.

7.0 Recommendations

7.1 The key findings of this study were:

1. Sub-standard documentation
2. High perinatal and neonatal mortality rates
3. The following features had a significant association with a poor perinatal outcome in the multivariate analysis:
 - Mothers who lived in rural and semi-urban environments
 - Parity of 5 and above
 - Breech delivery and CS delivery
 - Very low birth weight (< 1500g)
 - Low Apgar score at 5 minutes

7.2 Ways of addressing the key findings

7.2.1 Policy-makers

- There is need to **improve the referral system** for mothers with labour complications through formulation of referral policies and improvement of transport system. Emergency transport should be available around the clock in all health facilities. It was noted that some patients took a long time to get to the hospital and this could have resulted from lack of, or unclear, referral policy. Similarly, a poor transport system resulted to delayed arrival of patients at the tertiary level of care. Therefore, it is extremely important to have proper referral policies and quick and functional transport system so that patients are attended to at the next level of care before worsening of complications.

- Management guidelines and protocols: pre-transport management of sick and potentially unstable patients must be protocol driven. These protocols need to be written and implemented. The person or people responsible for writing the management protocols should be the obstetricians and paediatricians in the referral hospital. The protocols must be implemented in all health care facilities.
- Personnel allocation: The policy makers should allocate personnel in district hospitals with good clinical expertise. This would help most district hospitals to handle obstetric and neonatal emergencies at their own institutions thereby avoiding unnecessary referrals

7.2.2 District managers

- In-service training: District managers, together with facility managers, must be primarily responsible for the in-service training of the staff working in the health facilities in the district. The training must cover ante-natal care, management of labour, newborn resuscitation, and the care of the small and sick newborn baby. It must be clinically based and practical. It must also cover aspects on breech delivery and its guidelines related to the same. Part of this management is the documentation of the findings, the recognition of problems, and an understanding of the action which needs to be taken
- Resource allocation: District managers should allocate adequate resources towards maternal and neonatal services. These resources include staff, both medical and nursing, equipment, and resource and training material. This will help the hospital to render quality emergency obstetric care to pregnant mothers. Setting up a neonatal care unit can assist very sick newborns to receive specialized care which would increase the chances of survival.

- Improve family planning coverage: all women in the reproductive age should be counselled on family planning methods. And those with parity of 5 and above should be counselled on permanent sterilization (bilateral tubal ligation). This will help to reduce the risk of a PD which is high in women with parity of 5 and above.
- Perinatal review meetings: Initiate regular, non-threatening perinatal review meetings at the facility. The purpose of this is to:
 - Critically review all perinatal (and maternal) deaths
 - Assist in the accurate recording of all the perinatal statistics
 - Evaluate the perinatal statistics
 - In order to review the quality of patient care tools will be needed to be able to accurately assess patient records

This would assist health workers involved in offering the services to learn from PD reviews. Studies have shown that facilities that have this system in place experience fewer PDs.

7.2.3 Health facility staff

Health workers are responsible for the day to day running of the facility. This includes the clinical management of patients. They are responsible for:

1. Proper recording of patients information on the patient's record
2. Proper storage to ensure safety of the files. Although this does not directly affect PNMR but it can assist in the clinical management of patients, and clinical audit of management and outcomes, thereby leading to good quality of care which can result in the prevention of PDs.
3. They are responsible for maintaining and improving their own levels of clinical competence.

In view of the above mentioned aspects of care, there is need to arrange, or get someone else to arrange, appropriate in-service training to cover the aspects of care mentioned above. Ideally the clinical and nursing managers of the facility should take responsibility for this. There is a need to continuously assess the effectiveness of this approach.

7.2.4 Clients

There needs to be an emphasis on pregnant women attending antenatal clinic regularly. The aim should be for the women to attend at key points in their pregnancies when a health worker would spend time with them to screen for problems and to listen to the women's problems. At the ANC she should be equipped with adequate knowledge on the danger signs in pregnancy and labour complications and encouraged to come to the hospital early as this would enable problems to be managed early.

Clients should take an active role in increasing the usage of family planning methods. Mothers should be encouraged not to go beyond parity of 2 if possible.

7.2.5 Community

The communities should be encouraged to assist in making quick decisions in relation to referral of pregnant women. This can prevent delays in seeking maternal health care services at the first level of care and this will help women to reach health facilities before complications develop.

At community level it is also useful to identify people who could assist with emergency transport, should the need arise. These people should ensure that transport/money is always available whenever medical help is needed.

The community should ensure that women are accessing family planning services and husbands need to be involved in all family planning activities.

7.2.6 Research

The study had a low precision which was evidenced by wide confidence interval limits and some unusual results. There is need to carry out a similar study on the larger scale with an increased sample size (> 10, 000 deliveries). The study should be population based whereby deliveries from all health facilities would be combined with deliveries from the communities.

There is a need to look critically at the clinical problems which are occurring during antenatal care, labour and newborn care. These were not part of this study, but as it progressed, it became evident that only some associations were being looked at and it seemed that there were serious clinical problems underlying the problems. This needs to be addressed, but is something which the investigator considers to be the next step to try to improve perinatal care at KCH.

8.0 Conclusion

PNMR at KCH is higher than the national average. The high rate could be attributed to complicated cases handled by the hospital which are referred from other facilities. Some of the factors associated with perinatal deaths have been identified, and these have pointed to some specific areas of care which need attention. Therefore, improving health workers' skills in recognition of foetal problems during pregnancy and labour, improving family planning prevalence and perinatal care resource allocation coupled with good referral systems and timely interventions can help to prevent some of the avoidable PDs and subsequently leading to reduction of PNMR. This will help to the achievement of MDG number-4. This will need to be addressed at all levels of care, and not just the tertiary hospital.

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Appendices:

Appendix 1: Data sheet

Some of the associations with perinatal mortality at Kamuzu central hospital, Lilongwe, Malawi

1. Serial Number:

2. Registration Number:

Mother's demographics

2. Mother's age:

3. Residential area:

1	Urban	
2	Semi-urban	
3	Rural	

4. Mother's education level:

1	Formally educated	
2	Not formally educated	

5. Occupation:

1	Formally employed	
2	Not formally employed	

6. Parity:

1	
2	
3	
4	
≥ 5	

Antenatal care

7. Stillbirth (history)

1	Yes	
2	No	
3	N/Indicated	

8. Neonatal death (history)

1	Yes	
2	No	
3	N/Indicated	

9. Referral status

1	Yes	
---	-----	--

2	No	
---	----	--

10. Antenatal care attendance

1	Yes	
2	No	
3	N/Indicated	

11. If yes, specify number of times for ANC attendance:

12. HIV reactive

1	Yes	
2	No	
3	N/Indicated	

13. Completed weeks of gestation of pregnancy:

1	28-36 weeks	
2	37-42 weeks	
3	43 + weeks	
4	Unknown weeks	

Delivery Process

14. Labour induced

1	Yes	
2	No	

15. Mode of delivery:

1	SVD	
2	Breech	
3	A/E	
4	C/S	

16. Complications during labour:

1	Yes	
2	No	

If yes, indicate the type of complication

1	Haemorrhage	
2	Ruptured uterus	

3	Hypertension/Eclampsia	
4	Anaemia	
5	PROM	
6	Obstructed labour	
7	Other (specify)	

Other Specify:

Newborn health

17. Birth weight (g)

18. Sex of the newborn

1	Male	
2	Female	

19. Plurality of fetuses:

1	Singleton	
2	Twins	
3	Triplets	

20. Condition of newborn after delivery

1	Stillbirth	Macerated	Fresh
2	ENND		
3	Live birth		

If Stillbirth occurred, **STOP HERE**

21. APGAR score at 5 minutes:

1	1-3 minutes	
2	4-6 minutes	
3	7+ minutes	

22. Did ENND occur?

1	Yes	
---	-----	--

2	No	
---	----	--

If yes, number of days from delivery to death

Indicate cause of death (only one)

1	Prematurity	
2	Asphyxia	
3	Congenital abnormality	
4	Neonatal sepsis	
5	Hypothermia	
6	Syphilis	
7	Unknown	
8	Other (specify)	

Others specify:

University of Cape Town

Appendix 2: NHSRC approval letter

Telephone: + 265 789 400
Facsimile: + 265 789 431
e-mail doccentre@malawi.net
All Communications should be addressed to:
The Secretary for Health and Population



In reply please quote No. MED/4/36c

MINISTRY OF HEALTH

P.O. BOX 30377

LILONGWE 3

MALAWI

23rd September 2011

Elled Mwenyekonde
Kamuzu Central Hospital /University of Cape Town

Dear Sir,

RE: Protocol # 946: Assessing the determinants of perinatal mortality at Kamuzu Central Hospital in Lilongwe, Malawi

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has reviewed and **approved** your application to conduct the above titled study.

- **APPROVAL NUMBER** : NHSRC # 946
The above details should be used on all correspondence, consent forms and documents as appropriate.
- **APPROVAL DATE** : 23/9/2011
- **EXPIRATION DATE** : This approval expires on 22/09/2012
After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING** : All serious problems having to do with subject safety must be reported to the National Health Sciences Research Committee within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using standard forms obtainable from the NHSRC Secretariat is required before implementing any changes in the Protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on Telephone No. (01) 724418, 0999218630 or by e-mail on moh@gmail.com
- **Other**:
Please be reminded to send in copies of your final research results for our records as well as for the Health Research Database.

Kind regards from the NHSRC Secretariat.

FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

PROMOTING THE ETHICAL CONDUCT OF RESEARCH
Executive Committee: Dr. C. Mwanambwa (Chairman), Prof. Mfutso Bengo (Vice Chairperson)
Registered with the USA Office for Human Research Protections (OHRP) as an International IRB
(IRB Number IRB00003905 FWA00005976)

Appendix 3: University of Cape Town Research Ethics Committee approval letter



UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Faculty of Health Sciences Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

06 October 2011

HREC REF: 466/2011

Mr E Mwenyekonde
Adolescent & Child Health
Kamuzu Central Hospital
P.O.Box 149
Lilongwe, Malawi

Dear Mr Mwenyekonde

PROJECT TITLE: ASSESSING THE DETERMINANTS OF PERINATAL MORTALITY AT KAMUZU CENTRAL HOSPITAL IN LILONGWE, MALAWI

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 15 October 2012.

Please submit a progress form, using the standardised Annual Report Form (FHS016), if the study continues beyond the approval period. Please submit a Standard Closure form (FHS010) if the study is completed within the approval period.

Minor point: please note that we are called the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

sAriefdien

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

University of